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10/089,997	09/23/2002	Barrie Hayes-Gill	469.1094	5818

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EXAMINER

BERTRAM, ERIC D

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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06/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/089,997

Applicant(s)

HAYES-GILL ET AL.

Examiner

Eric D. Bertram

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-42 is/are rejected.
- 7) ☒ Claim(s) 43-47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 10/26/2006 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that only the abdominal ECG signal is utilized to determine the fetal and maternal heart rates) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Nowhere in the claims is it recited that only abdominal ECG signals are used, merely that only processed ECG signals are used. Furthermore, claim 1 recites a detector that is adapted to be positioned on the abdomen of the mother in use. As admitted by the applicant on page 7 of the Remarks, both Greenberg and Baker disclose a detector that is placed in the abdominal area. Therefore, even though there are also parts of the detector placed on the chest, the limitation is still met since the transitional phrase of the preamble is "comprising." Since Greenberg and Baker only utilize processed ECG signals to determine the heart rates of the fetus and the mother, the 35 USC 102 and 103 rejections are still considered proper.

Claim Rejections - 35 USC § 112

2. The amendments and arguments regarding the 35 USC 112(1) rejection of claims 35 and 38 are persuasive, and the rejection has been withdrawn.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 25-32, 40 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative as being unpatentable over Greenberg et al. (US 6,751,498).

5. Greenberg et al. discloses an apparatus for detecting fetal and/or maternal heart rate (see col. 4, lines 1-14). Fetal and/or maternal ECG activity may be detected with the array of electrodes (see col. 2, lines 50-55), and processor circuitry may be used to derive the fetal heart rate and the maternal heart rate (see col. 2, lines 57-60). Lewis et al. does not specifically disclose that the processor utilizes ECG peaks and corresponding time intervals in order to determine the maternal heart rate. However, detection of heart rate from an ECG waveform necessarily utilizes ECG peaks and

Art Unit: 3762

corresponding time intervals. In the alternative, it is well known in the art to detect heart beats of the mother by determining when the ECG peaks reach a maximum (i.e., ECG peaks) and to determine the time interval between adjacent heart beats (i.e., corresponding time intervals between ECG peaks) so as to determine the heart rate of the mother. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Greenberg et al. such that detection of the maternal heart rate from an ECG waveform utilizes ECG peaks and corresponding time intervals in order to determine the maternal heart rate by well known and accepted medical methods.

6. With respect to claim 26, Greenberg et al. discloses that the array of electrodes includes at least two detectors to detect the heart beats of the fetus, each detector including at least two electrodes (for example, electrode strip sensors 34 and 36 each contain a plurality of electrodes; see col. 9, line 50 - col. 10, line 15).

7. With respect to claims 28-29, Greenberg et al. discloses that a reference fetal waveform is processed against the other abdominal waveforms in order to form an enhanced fetal signal that is a representation of the fetal ECG (see col. 4, lines 34-42 and col. 7, lines 1-48). Examiner considers this fetal ECG to be a virtual ECG signal that is a weighted sum of the ECG signals detected by the detectors.

8. With respect to claims 30 and 32, Greenberg et al. discloses signal processing for amplifying and filtering the ECG signals.

9. With respect to claim 31, Greenberg et al. discloses that the ECG signals may be displayed (see col. 7, lines 49-64).

10. With respect to claim 40, Greenberg et al. discloses suppression of the maternal ECG in order to detect the fetal ECG (see, for example, col. 4, lines 34-52).
11. With respect to claim 42, Examiner considers the apparatus portable.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 25-27, 30-32, and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,781,200 ("Baker").
14. Baker discloses an apparatus for detecting the heart rate of a fetus (fetal monitoring system 20), including at least two electrodes positioned on the abdomen of the mother in use for detecting ECG signals (plurality of fetal monitoring sensors 35 may be ECG sensors; see col. 5, lines 1-5), a processor for receiving the signals received from each detector and determining the heart rate of the fetus (control unit 40; see col. 7, lines 20-35). Baker does not specifically disclose that control unit 40 may also determine the heart rate of the mother. However, it is well known in the art to monitor the maternal heart rate in addition to monitoring the fetal heart rate (i.e., see U.S. Patent No. 5,666,959 which teaches a method and apparatus for deriving a fetal heart rate and a maternal heart rate). It would have been obvious to one having ordinary skill in the art

Art Unit: 3762

at the time of applicant's invention to modify the monitoring device of Baker such that it also monitors the maternal heart rate (utilizing the detected maternal ECG) in order to monitor the well being of the mother during pregnancy and labor.

15. With respect to claim 27, Baker fails to specifically disclose that a common electrode forms one of the electrodes of each detector. It is known in the art to utilize a common reference electrode (see "Lead systems for the abdominal fetal electrocardiogram," which teaches multiple lead configurations for detecting a fetal ECG. The article describes one proposed configuration in which an array of electrodes is placed over the abdomen, unipolar signals are recorded with the common reference being at the lower abdomen (see page 24, fifth full paragraph)). It would have been obvious to one having ordinary skill at the time of applicant's invention to form a common electrode for the multiple sensors of Baker in order to reduce the number of required electrodes.

16. With respect to claims 30 and 32, Baker discloses a signal processor for amplifying and filtering the ECG signals detected by the detectors (see Figures 6A-6C and associated text).

17. With respect to claim 31, the control unit 40 of Baker includes a visual display (73) of fetal heart rate and can further display other information such as patient history (see col. 6, lines 57-65). Baker fails to specifically disclose that ECG signals or traces can be displayed on display 73. Displaying dynamic ECG traces is well known in the art. It would have been obvious to one having ordinary skill at the time of applicant's invention to modify the system of Baker to include such a display in order to provide an

Art Unit: 3762

operator with the morphology of the ECG trace that may be utilized to detect further abnormalities.

18. With respect to claim 40, Baker determines the heart rate of the fetus by suppressing the maternal signal (see col. 8, lines 20-40 or col. 10, lines 55-65), detecting peaks of the remaining fetal signal (via peak value processor 183), and determining the time interval between adjacent beats (see col. 18, lines 35-55).

19. With respect to claim 41, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to aggregate the heart rate over a predetermined time period in order to detect sustained low or high fetal heart rates (i.e., see Baker at col. 7, lines 25-29).

20. With respect to claim 42, the apparatus is portable (see Figs. 1 and 2).

21. Claims 33-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker in view of U.S. Patent No. 6,115,624 ("Lewis et al.").

22. With respect to claims 33 and 35, Baker, as described above, discloses the applicant's basic invention with the exception of correlating a maternal template with a filtered ECG signal. Attention is directed to the secondary reference of Lewis et al., which teaches that the processor circuitry may compare the detected signals to a database stored in the memory circuitry to further facilitate the heart rate information in the signals. For example, the database may include information such as standard maternal and/or fetal heart signals which may be compared to the detected signals (see col. 10, lines 43-51). Therefore, it would have been obvious to one of ordinary skill in

Art Unit: 3762

that art at the time of the applicant's invention to modify the system of Baker by utilizing the maternal templates of Lewis in order to more accurately derive the desired actual heart rate.

23. With respect to claims 34 and a portion of claim 40, Baker discloses subtracting a maternal component from a composite ECG in order to obtain the fetal ECG only (e.g., see U.S. Patent No. 4,781,200 to Baker at col. 8, lines 20-40 or col. 10, lines 55-65).

24. With respect to claims 36 and 37, bandpass filters are well known to filter noise components from a detected ECG. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Baker, as modified, such that bandpass filters are utilized in the signal processing of the ECG in order to reduce noise and obtain a more accurate ECG signal.

25. With respect to claims 38-39 and a portion of claim 40, Lewis et al. discloses that the processor circuitry may be used to derive the fetal heart rate and the maternal heart rate (see col. 2, lines 57-60). Lewis et al. does not specifically disclose that the processor utilizes ECG peaks in order to determine the fetal heart rate. However, detection of heart rate from an ECG waveform necessarily utilizes ECG peaks and corresponding time intervals. In the alternative, it is well known in the art to detect heart beats by determining when the ECG peaks reach a maximum (i.e., ECG peaks) and to determine the time interval between adjacent heart beats (i.e., corresponding time intervals between ECG peaks) so as to determine the heart rate of the mother. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the monitoring device of Lewis et al. such that detection of the fetal

Art Unit: 3762

heart rate from an ECG waveform utilizes ECG peaks and corresponding time intervals in order to determine the fetal heart rate by well known and accepted medical methods.

26. With respect to claim 41, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to aggregate the heart rate over a predetermined time period in order to detect sustained low or high fetal heart rates.

Allowable Subject Matter

27. Claims 43-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3762

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

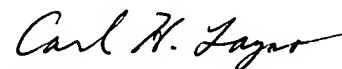
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday through Thursday, 8 a.m. to 6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CARL LAYNO
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